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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,958	08/13/2001	Masayoshi Nanba	2519US0P	8993
23115	7590	03/31/2005	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 03/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/673,958		NANBA ET AL	
	<b>Examiner</b>		<b>Art Unit</b>	
	Brian Whiteman		1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/14/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Final Rejection**

Claims 1, 2, and 5 are pending.

Applicants' traversal and the amendment to claim 1 in paper filed on 1/10/05 is acknowledged and considered.

### ***Claim Objections***

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The amendment to claim 1 limits the retained enzyme activity to CYP1A1, CYP1A2, and CYP3A, however claim 2 (which depends on claim 1) recites that the retained enzyme activity is NADPH cytochrome P450 reductase activity, glucuronosyl transferase activity, ethoxyresorufine dealkylation activity, benzyloxyresorufme dealkylation activity, pentoxylresorufme dealkylation activity or methoxyresorufme dealkylation. Thus, in view of the term "the retained enzyme activity" on line 1 of Claim 2, claim 2 does not recite that the retained enzyme activity includes CYP1A1, CYP1A2, and CYP3A.

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pfeifer et al. (PNAS, Vol. 90, pages 5123-5127, cited on a previous PTO-892).

Instant claim 1 reads on an immortalized hepatocyte cell culture of human normal cell origin retaining the capability of expressing genes encoding enzymes involved in the metabolism of xenobiotics in the liver, wherein said enzymes are CYP1A1, CYP1A2, and CYP3A. In view of the term “capability”, the cell line is not required to express said enzymes.

In view of the objection to claim 2 and compact prosecution, claim 2 could read on either 1) the cell line of claim 1 further comprising an enzyme activity selected from NADPH cytochrome P450 reductase activity, glucuronosyl transferase activity, ethoxyresorufine dealkylation activity, benzyloxyresorufme dealkylation activity, pentoxylresorufme dealkylation activity or methoxyresorufme dealkylation or 2) An immortalized hepatocyte cell culture of human normal cell origin retaining enzyme activity NADPH cytochrome P450 reductase activity, glucuronosyl transferase activity, ethoxyresorufine dealkylation activity, benzyloxyresorufme dealkylation activity, pentoxylresorufme dealkylation activity or methoxyresorufme dealkylation.

Pfeifer anticipates the immortalized hepatocyte cell culture in claim 1. Pfeifer teaches immortalized human liver cell culture that expresses hepatocyte characteristics (abstract). The

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liver cell culture taught by Pfeifer expresses CYP1A1/1A2, epoxide hydrolase, NADPH CYP reductase, SOD, catalase, glutathione S-transferase, and glutathione peroxidase (pages 5126-5127).

Pfeifer anticipates claim 2 because Pfeifer teaches that the immortalized human liver cell culture further retains NADPH CYP reductase (NADPH cytochrome P450 reductase) (pages 5126-5127).

Applicant's arguments filed 1/10/05 have been fully considered but they are not persuasive because in view of the "capability" in the claims, the claims do not require that the cell line in the cell culture express CYP1A1, CYP1A2, and CYP3A.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

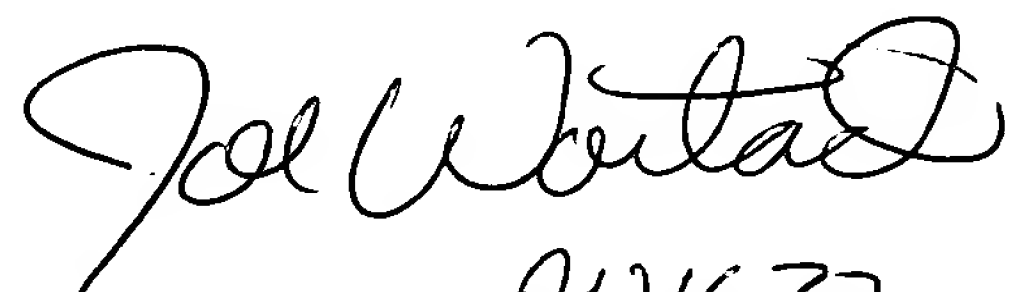
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman  
Patent Examiner, Group 1635



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